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10/552,366	10/03/2005	Faramarz Jadidi	HOI-27702/16	8303

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EXAMINER
SZMAL, BRIAN SCOTT

ART UNIT	PAPER NUMBER
3736	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE <u>3</u> MONTH(S) OR THIRTY (30) DAYS,
WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.
- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed
  after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
  Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any
  earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on <u>19 April 2011</u>.

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is
closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) <u>85-111</u> is/are pending in the application.

    4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) <u>85-111</u> is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☒ The drawing(s) filed on <u>03 October 2005</u> is/are: a)☒ accepted or b)☐ objected to by the Examiner.

    Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

    Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

    a)☒ All b)☐ Some * c)☐ None of:

      1.☒ Certified copies of the priority documents have been received.

      2.☐ Certified copies of the priority documents have been received in Application No. _____.

      3.☐ Copies of the certified copies of the priority documents have been received in this National Stage
      application from the International Bureau (PCT Rule 17.2(a)).

    * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)

2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)

3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>5/24/11</u>.

4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.

5) ☐ Notice of Informal Patent Application

6) ☐ Other: _____.

Continued Examination Under 37 CFR 1.114

1.   A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on April 19, 2011 has been entered.

Claim Rejections - 35 USC § 112

2.   The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3.   Claims 106-108 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

    Each of the claims fails to clearly set forth the metes and bounds of the claims. The claims comprise functional language that can be reasonably interpreted as method steps for performing frequency pattern recognition. Since the claims are directed towards an apparatus, and the functional language constitutes method steps, the metes and bounds of the claims are not clearly set forth.

Claim Rejections - 35 USC § 103

4.   The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all

obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set
> forth in section 102 of this title, if the differences between the subject matter sought to be patented and
> the prior art are such that the subject matter as a whole would have been obvious at the time the
> invention was made to a person having ordinary skill in the art to which said subject matter pertains.
> Patentability shall not be negatived by the manner in which the invention was made.

5.   Claims 85-93, 99, 102-104 and 109-111 are rejected under 35 U.S.C. 103(a) as

being unpatentable over Ober (4,669,477) in view of Lavigne et al (Sleep Bruxism:

Validity of Clinical Research…1995).

Ober discloses a means for preventing bruxism and further discloses a sensor

system operable in a setup mode for sensing muscular activity of the jaw to measure a

first level of muscular activity associated with a level of biting force; the sensor system

being further operable in a use mode to measure the muscular activity of the jaw and to

generate a signal corresponding thereto; a signal processor in communication with the

sensor system and which is operable to receive the signals and calculate a threshold

level of the muscular activity; a feedback generator in communication with the signal

processor and sensor system, the feedback generator being operable to receive the

third signal and generate a feedback signal is the sensor system is operating in the use

mode and if the level of muscular activity exceeds the threshold level calculated by the

signal processor; the feedback generator is operable to generate the feedback signal

only if the measured level of activity exceeds the threshold for a predetermined period

of time; the feedback generator includes a control system for controlling the intensity of

the signal; the sensor system is operable to detect EMG signals; the apparatus is

operable to store data derived from the sensor system and/or the signal processor

and/or the feedback generator; the apparatus is operable to store the threshold in an associated memory; the signal processor is operable to determine the amplitude of the frequency content of signals from the sensor system; the signal processor is operable to carry out low pass filtering of the signals form the sensor system to filter out noise and unusable signals; and the signal processor is operable to rectify signals from the sensor system. See Column 2, lines 38-42 and 49-68; Column 3, lines 1-12 and 60-68; and Column 4, lines 1-4; in Column 3, lines 8-12, indicate the threshold can be adjusted via threshold control 32 to provide a desired predetermined level of jaw activity. This also indicates the device is setup prior to actual use and each device would be individually setup to each person.

Ober, while disclosing the ability to setup the device, fails to explicitly disclose measuring a first level of muscle activity to generate a first signal; measuring a second level if muscle activity associated with a normally occurring jaw activity and generating a second signal; calculating a threshold that is less than 100% of the first level of muscular activity, but more than the second level of muscular activity; the signal processor is operable to calculate a threshold level in the range of 3-20% of the first level of activity; the first level of activity is associated with a maximum bite force; the second level of activity is associated with a grimace; the sensor system is operable to detect acoustic signals.

Lavigne et al disclose the ability to detect bruxism and further disclose measuring a first level of muscle activity to generate a first signal (p 548, second paragraph); measuring a second level if muscle activity associated with a normally occurring jaw

activity and generating a second signal (p 548, second paragraph); calculating a threshold that is less than 100% of the first level of muscular activity, but more than the second level of muscular activity (p 548, second paragraph); the signal processor is operable to calculate a threshold level in the range of 3-20% of the first level of activity (p 548, second paragraph); the first level of activity is associated with a maximum bite force; the second level of activity is associated with a grimace (p 547, second column, second paragraph; the "rhythmic contractions" encompass a grimace); the sensor system is operable to detect acoustic signals (p 548, second paragraph).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the means of Ober to measure the signal response of a maximum bite force and a grimace as part of the setup of the device for calibrating the device for a specific user, as per the teachings of Lavigne et al, since it would provide a means of accurately setting up the device for measuring an individual's jaw movements. It also would have been obvious to one of ordinary skill in the art to automate the threshold determination in Ober, since automating a manual process is a design consideration to one of ordinary skill in the art. See In re Venner.

6.   Claims 94, 95 and 97 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Lavigne et al (Sleep Bruxism: Validity of Clinical Research...1995) as applied to claim 85 above, and further in view of Weinstein et al (6,270,466 B1).

Ober and Lavigne et al, as discussed above, disclose a means for detecting a bruxism event and providing feedback to the user, but fail to disclose a computer for

transferring the stored data thereto; the user module is adapted to be worn on the head

of the user; and a display operable to display information and/or results derived from the

sensor system and/or signal processor and/or threshold generator.

Weinstein et al disclose a bruxism feedback device and further disclose a

computer for transferring the stored data thereto; the user module is adapted to be worn

on the head of the user; and a display (D, 102) operable to display information and/or

results derived from the sensor system and/or signal processor and/or threshold

generator. See Figures 2 and 5C.

It would have been obvious to one of ordinary skill in the art at the time the

invention was made to modify the combination of Ober and Lavigne et al to transfer the

acquired data to a computer, wearing the system on the head and displaying

information on a display, as per the teachings of Weinstein et al, since it would provide

a means of further processing the signal data, provide a unitary structure that is located

on the head, and allow the user to readily ascertain how many bruxism events occurred

during their sleep.

7.   Claim 96 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober

(4,669,477) and Lavigne et al (Sleep Bruxism: Validity of Clinical Research…1995) as

applied to claim 85 above, and further in view of Sunouchi et al (5,368,043).

Ober and Lavigne et al, as discussed above, disclose a means for preventing

bruxism, but fail to disclose the apparatus comprises a slave module and a master

module, the slave module being designed for wearing by a patient.

Sunouchi et al disclose a means for measuring muscle activity and further disclose the apparatus comprises a slave module and a master module, the slave module being designed for wearing by a patient (the patient unit acquires data and transmits the data to the CPU 20 for processing and display; therefore the patient unit is the slave unit and the CPU is the master unit). See Column 6, lines 65-68; and Column 9, lines 18-27.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Lavigne et al to include the use of a computer within a slave/master unit setup, as per the teachings of Sunouchi et al, since it would provide an external processing means to process the data and control the feedback means.

8.   Claims 98, 101, 105 and 106 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Lavigne et al (Sleep Bruxism: Validity of Clinical Research...1995) as applied to claim 85 above, and further in view of Massicotte et al (2004/0068196 A1).

Ober and Lavigne et al, as discussed above, disclose a means for treating bruxism using acquired EMG signals and providing feedback based on the acquired signals, but fail to disclose the apparatus is configured for frequency pattern recognition of the signals; and the frequency pattern recognition includes comparing the frequency content of the signals to the stored frequency pattern.

Massicotte et al disclose a means for trend detection in a monitoring signal and further disclose the apparatus is configured for frequency pattern recognition of the

signals; and the frequency pattern recognition includes comparing the frequency content of the signals to the stored frequency pattern. See Paragraph 0057.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Ober and Lavigne et al to include the use of frequency pattern recognition and comparing the frequency content of the acquired signals to the stored signals, as per the teachings of Massicotte et al, since it would provide a computer based means to recognize specific signals indicating a bruxism event, such that the user can be provided feedback to arrest the bruxism event.

9.   Claim 100 is rejected under 35 U.S.C. 103(a) as being unpatentable over Ober (4,669,477) and Lavigne et al (Sleep Bruxism: Validity of Clinical Research...1995) as applied to claim 85 above, and further in view of Prass (6,306,100 B1).

Ober and Lavigne et al, as discussed above, disclose a means for treating bruxism, but fail to teach the stored signals indicative of muscle activity are processed by FFT analysis.

Prass discloses a means for neurophysiological monitoring and further disclose the stored signals indicative of muscle activity are processed by FFT analysis. See Column 37, lines 52-59.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the combination of Weinstein et al and Ober, to include the use of FFT analysis on the stored EMG signals, as per the teachings of Prass, since it would provide a means for performing frequency analysis on the acquired EMG signals.

10.   Claims 107 and 108 are rejected under 35 U.S.C. 103(a) as being unpatentable

over Ober (4,669,477), Lavigne et al (Sleep Bruxism: Validity of Clinical

Research…1995) and Massicotte et al (2004/0068196 A1) as applied to claim 101

above, and further in view of Hine et al (5,877,444).

        Ober and Lavigne et al, as discussed above, disclose a means for treating

bruxism using acquired EMG signals and providing feedback based on the acquired

signals, but fail to disclose the frequency pattern recognition includes comparing one or

more harmonic frequencies of the signals to the stored frequency pattern; and the first

harmonic frequency (fundamental frequency) is compared to the stored frequency

pattern.

        Hine et al disclose a tuner for instruments and further disclose the frequency

pattern recognition includes comparing one or more harmonic frequencies of the signals

to the stored frequency pattern; and the first harmonic frequency (fundamental

frequency) is compared to the stored frequency pattern. See Column 2, lines 46-53.

        Even though Hine et al discloses a means for tuning instruments, Hine et al

demonstrates that it is well known to acquire the first harmonic frequency of a signal

and compare it to a stored frequency pattern to provide a diagnosis. Therefore it would

have been obvious to one of ordinary skill in the art at the time the invention was made

to modify the combination of Ober and Lavigne et al to include comparing the first

harmonic frequency of the acquired signal to a stored frequency pattern, as per the

teachings of Hine et al, since it would provide a means of accurately providing feedback

to a user suffering from bruxism.

Response to Arguments

11.   Applicant's arguments filed April 19, 2011 have been fully considered but they are not persuasive.

The Applicant first argues the threshold setting in Ober is a manual process, and Ober fails to disclose the claimed threshold determination process. The Applicant further states the Examiner clearly states Ober fails to teach any of the threshold determination steps. The Examiner respectfully disagrees. The Examiner states in the rejection that "Ober...fails to *explicitly disclose*..." the claimed threshold limitations. {emphasis added} Ober does not explicitly or inherently disclose the claimed threshold determination steps, but does disclose the ability to manually set a threshold. The Examiner would also like to note the replacement of a manual determination of a threshold with an automatic determination is a design consideration to one of ordinary skill in the art. The prior art of Lavigne et al disclose the measurement of EMG signals to recognize the occurrence of a bruxism event, thus providing a threshold for determining bruxism.

The Applicant then argues the prior art of Lavigne et al fails to disclose the claimed threshold determination and also fails to teach a means for managing bruxism. The Examiner respectfully disagrees. Lavigne et al teach prior to sleep recordings, a plurality of controlled muscle measurements are taken. These measurements are then used later in the analysis of the acquired sleep data to diagnose the presence of bruxism. The measurements prior to the sleep study are baseline measurements, which

are used to determine the presence of a bruxism event in the patient. Therefore the baseline measurement is a threshold.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., a real-time analysis or assessment of data to determine a bruxism event) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The current claim language only requires the measurement of EMG data and providing a feedback based on the measurement; the feedback does not have to occur based on real-time events.

In response to applicant's argument that Lavigne et al is nonanalogous art, it has been held that a prior art reference must either be in the field of applicant's endeavor or, if not, then be reasonably pertinent to the particular problem with which the applicant was concerned, in order to be relied upon as a basis for rejection of the claimed invention. See *In re Oetiker*, 977 F.2d 1443, 24 USPQ2d 1443 (Fed. Cir. 1992). In this case, Lavigne et al disclose the measurement of jaw muscle activity prior to a sleep study to determine the occurrence of a bruxism event.

The Applicant further argues the prior art of Lavigne et al is directed towards acquiring jaw muscle activity data to diagnose bruxism, but not control bruxism; therefore further teaching away from the claimed invention. The Examiner respectfully disagrees. The rejection of the independent claims is based on the combination of Ober and Lavigne et al. The prior art of Ober is based on the measurement of jaw muscle

activity signals, comparing the measured signals to a threshold, and providing a feedback to the user to stop the bruxism event. The comparison of the measured jaw muscles to a threshold constitutes a diagnosis, much in the same way the prior art of Lavigne et al diagnosis a bruxism event.

In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., providing an immediate feedback signal to end an episode of bruxism) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993).

The Applicant further argues the teachings of Ober and Lavigne et al are directed towards "very different aspects of bruxism", with Ober focused on treatment, and Lavigne et al focused on diagnosis. The Applicant further argues neither Ober nor Lavigne et al teach the determination of the claimed threshold. The Examiner respectfully disagrees. The prior art of Ober would be incapable of functioning as a bruxism treatment means if there was not any diagnosis of a bruxism event in the first place. The prior art of Lavigne et al disclose the use of baseline measurements (thresholds) to diagnose bruxism from later-acquired jaw muscle activity signals during a sleep study. Therefore, Ober provides the teaching for the combining the prior art of Ober with the prior art of Lavigne et al.

   Any inquiry concerning this communication or earlier communications from the
examiner should be directed to Brian Szmal whose telephone number is (571)272-4733.
The examiner can normally be reached on Monday-Friday, with second Fridays off.

   If attempts to reach the examiner by telephone are unsuccessful, the examiner's
supervisor, Max Hindenburg can be reached on (571) 272-4726. The fax phone
number for the organization where this application or proceeding is assigned is 571-
273-8300.

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/Brian Szmal/
Examiner, Art Unit 3736